Jeanne F. Loftis, OSB #913612
Email: jeanne.loftis@bullivant.com
Nelly F. Greenberg, OSB #201968
Email: nelly.greenberg@bullivant.com
BULLIVANT HOUSER BAILEY PC
One SW Columbia Street, Suite 800
Portland, Oregon 97204-4022
Telephone: 503.228.6351
Facsimile: 503.295.0915

Anita Modak-Truran (admitted *pro hac vice*)
Email: anita.modak-truran@butlersnow.com
Kenneth Conour (admitted *pro hac vice*)
Email: kenneth.conour@butlersnow.com
Jin Yoshikawa (admitted *pro hac vice*)
Email: jin.yoshikawa@butlersnow.com
BUTLER SNOW, LLP
150 3rd Avenue South, Suite 1600
Nashville, Tennessee 37201
Telephone: 615.651.6751

Attorneys for Defendants Ethicon, Inc. and Johnson & Johnson

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

BARBARA SMITH and GARY SMITH, Plaintiffs, v. ETHICON, INC., ETHICON LLC and JOHNSON & JOHNSON, Defendants.	Civil No.: 3:20-cv-00851-MO **DEFENDANTS' PROPOSED BEGINNING-OF-CASE JURY INSTRUCTIONS**

Pursuant to Rule 51 of the Federal Rules of Civil Procedure, Local Rules 51(b)-(d) of the Local Rules of the U.S. District Court for the District of Oregon, this Court's Amended Trial Management Order (Dkt. 193), and this Court's statements at the May 31, 2022 hearing, Defendants Ethicon, Inc. and Johnson & Johnson ("Defendants") hereby submit a revised set of beginning-of-case instructions ("Proposed Instructions") on the substance of the parties' claims and defenses. In addition to these substantive instructions, and as previously agreed upon by the parties, Defendants request that the Court include Ninth Circuit Model Civil Jury Instruction Nos. 1.2, 1.6, 1.7, 1.8, 1.9, 1.10, 1.11, 1.12, 1.13, 1.14, 1.15, 1.16, 1.17, 1.18, 1.19, 1.20, 1.21, 2.2, 2.4, 2.9, 2.13, 2.14, 2.15 and 3.2, in that order, before the substantive instructions proposed below.

Defendants submit these Proposed Instructions prior to rulings concerning, among other things, motions *in limine*, deposition designations, and evidentiary objections at trial, and without knowing precisely which witnesses will be called at trial or the exact claims that will be submitted to the jury following a ruling on Defendants' motions for nonsuit and/or instructed verdict. By submitting these Proposed Instructions, Defendants do not waive any defense or argument, nor do Defendants concede there is any fact issue on any question pertaining to either liability or damages. To the contrary, Defendants maintain they are entitled to a take-nothing judgment.

Defendants reserve the right to seek nonsuit, directed verdict, j.n.o.v., and any other appropriate relief during or after trial. In addition, Defendants reserve the right to amend, modify, clarify, or supplement these Proposed Instructions as necessary. Defendants specifically reserve the right to offer additional instructions as necessary, including in the event

the Court concludes that issues not reflected in these Proposed Instructions will be tried to the jury.

DEFENDANTS' PROPOSED INSTRUCTION NO. 1

(Parties' Claims and Defenses)

The plaintiff in this case is Barbara Smith. The defendants are Ethicon, Inc. and Johnson & Johnson. Though I may refer to Ethicon, Inc. and Johnson & Johnson as "Defendants" in my instructions, you should decide the case as to each defendant separately as I previously explained.

Plaintiff asserts that the Prolift medical device sold by Defendants and implanted to treat her pelvic organ prolapse injured her. Plaintiff makes the following claims:

(1) That Defendants were negligent in designing Prolift and warning about its risks;

(2) That the Prolift mesh device was defective;

(3) That Defendants defrauded Plaintiff; and

(4) That Defendants breached express or implied warranties regarding the Prolift mesh device.

Defendants deny these claims. They assert that Plaintiff's alleged injuries are instead due to other causes, including her own actions. Defendants also maintain that Plaintiff failed to mitigate her damages, and that her claims were not timely filed.

I will instruct you and explain the law regarding each of these claims and defenses separately. You will then consider and decide each of those claims and defenses.[1]

[1] Manual of Model Civil Jury Instructions, Ninth Circuit, No. 1.5 (modified).

DEFENDANTS' PROPOSED INSTRUCTION NO. 2

(Learned Intermediary Doctrine)

A number of Plaintiff's claims relate to warnings and statements Defendants made regarding the risks and benefits of the Prolift device. That includes Plaintiff's claims for negligence, strict liability, fraud, and breach of warranty.

Under each of those claims, however, the manufacturer of a prescription medical device such as Prolift has no duty to warn patients directly. The manufacturer only has a duty to provide an adequate warning to the prescribing physician. That is because the law assumes that, before a physician prescribes a product to a patient, the physician will communicate that product's risks to the patient. This means that, if you find that Defendants adequately warned physicians of the risks of the Prolift device, you must find for Defendants on Plaintiff's claims based on the assertion that Defendants inadequately warned of Prolift's risks.[2]

[2] *Oksenholt v. Lederle Laboratories*, 656 P.2d 293, 296-97 (Or. 1982); *Vaughn v. G.D. Searle & Co.*, 536 P.2d 1247, 1247-48 (Or. 1975); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974); *Parkinson v. Novartis Pharmaceuticals, Corp.*, 5 F. Supp. 3d 1265, 1273 (D. Or. 2014); *Bellew v. Ethicon, Inc.*, 2014 WL 6886129, at *5–6 (S.D.W. Va. Nov. 24, 2014) (Goodwin, J.) ("If the learned intermediary doctrine 'could be avoided by casting what is essentially a failure to warn claim under a different cause of action . . . then the doctrine would be rendered meaningless.'" (citation omitted)); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 986, 989 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659, 660–61 (9th Cir. 2004) (learned intermediary doctrine applies to product liability claims challenging the adequacy of a product's warnings, regardless of the theory attached, be it strict liability, negligence, breach of warranty, or fraud); *Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001) (noting learned intermediary doctrine "is supported by comment (k) to the § 402A of the Restatement (Second) of Torts"); *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 977-78 (Wash. 1978) (applying learned intermediary doctrine to strict liability claims governed by Restatement (Second) of Torts § 402A). While Plaintiff might argue that Oregon abolished the learned intermediary rule in strict liability cases, citing *Griffith v. Blatt*, 51 P.3d 1256 (Or. 2002), that is not so. *Griffith* held only that the learned intermediary rule "does not create a defense to strict liability" when applied to *pharmacists* who dispensed the product. *See id.* at 1258, 1262 ("Neither the text nor the context of

[Oregon's product liability] statutes indicates that the legislature intended to relieve a seller from potential strict product liability on the basis of the adequacy of a manufacturer's product warnings to another intermediary (here, the physician)."). It said nothing of the doctrine's application to manufacturers of pharmaceutical products. *See id.* In fact, the *Griffith* court had no occasion to consider that question because the manufacturer defendant had been dismissed on the statute of limitations. *See id.* at 1261.

DEFENDANTS' PROPOSED INSTRUCTION NO. 3

(No Duty to Warn About Known Risks)

Medical device manufacturers are not required to warn of a risk generally known to the physicians that prescribe those devices. Physicians are assumed to have general knowledge about particular medical risks due to their medical training and experience and the information that is available in medical literature. Defendants thus had no duty to warn of any risk of the Prolift device that was generally known to pelvic floor surgeons. Therefore, when deciding whether Defendants' warnings were adequate, you must consider what information Defendants could reasonably have assumed Plaintiff's implanting physician possessed about the risks of Prolift devices based on his education, training, and experience as a pelvic floor surgeon.[3]

[3] O.R.S. § 30.920(3); Restatement (Second) of Torts § 402A, cmt. *j* (1965); *Gunstone v. Julius Blum GMbH*, 825 P.2d 1389, 1392 (Or. Ct. App.), *rev. denied*, 833 P.2d 1283 (Or. 1992); *Crosswhite v. Jumpking, Inc*., 411 F. Supp. 2d 1228, 1235 (D. Or. 2006); *Alton v. Medtronic, Inc*., 970 F. Supp. 2d 1069, 1100 (D. Or. 2013).

DEFENDANTS' PROPOSED INSTRUCTION NO. 4

(Negligence)

I will now explain certain concepts related to Plaintiff's negligence claim.

Plaintiff has made a claim for negligence against Defendants based on their design of and warnings regarding the risks of the Prolift device. This requires Plaintiff to prove each of the following:

(1) Defendants' conduct in designing the Prolift or warning about its risks was negligent;

(2) Defendants' negligent conduct caused harm to Plaintiff; and

(3) The harm to Plaintiff was reasonably foreseeable.[4]

[4] Oregon Uniform Civil Jury Instruction No. 20.01, 20.02.

DEFENDANTS' PROPOSED INSTRUCTION NO. 5

(Negligence: Negligent Conduct Defined)

The law requires every person to use "reasonable care" to avoid harming others. A defendant's conduct is negligent if it fails to use "reasonable care."

"Reasonable care" is the degree of care and judgment used by reasonably careful people to avoid harming themselves or others. A person fails to use reasonable care when they do something that a reasonably careful person would not do, or fails to do something that a reasonably careful person would do, under similar circumstances. A medical device manufacturer is negligent if it fails to use the amount of care in designing or warning about a product that a reasonably careful medical device manufacturer would use in similar circumstances.

In deciding whether Defendants used "reasonable care" in designing the Prolift device or warning about the device's risks, do not judge their conduct in light of later events. Instead, consider what Defendants knew or should have known at the time they designed the device and warned about its risks, and whether they failed to use the amount of care in designing or warning about a product that a reasonably careful medical device manufacturer would use in similar circumstances.[5]

[5] Oregon Uniform Civil Jury Instruction No. 20.02; *Scott v. C.R. Bard, Inc*., 774, 180 Cal. Rptr. 3d 479, 489 (Cal. Ct. App. 2014); *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 548 F. Supp. 3d 1225, 1250 (S.D. Fla. 2021); *In re: E. I. Du Pont De Nemours & Co. C-8 Pers. Inj. Litig.*, 2016 WL 659112, at *13 (S.D. Ohio Feb. 17, 2016).

DEFENDANTS' PROPOSED INSTRUCTION NO. 6

(Negligence: Customs and Practices)

In deciding whether Defendants acted with "reasonable care," you may also consider the customs and practices common to the similar medical device manufacturers.

Customs and practices do not necessarily determine what a reasonable person would have done in the parties' situation. They are only factors for you to consider. Following a custom or practice does not excuse conduct that is unreasonable. You should consider whether the custom or practice itself is reasonable.[6]

[6] *Robbins v. Steve Wilson Co*., 463 P.2d 585, 587 (Or. 1970) (en banc); Restatement (Second) of Torts § 295A (1965); *Bullis v. Security Pac. Nat. Bank*, 582 P.2d 109, 112–13 (Cal. 1978); *Ponce v. Mountaineers*, 190 Wash. App. 1048, 2015 WL 6684507, at *3 (Wash. Ct. App. 2015).

DEFENDANTS' PROPOSED INSTRUCTION NO. 7

(Negligence: State of the Art)

Manufacturing standards, and what constitutes "reasonable care" among medical device manufacturers, can change over time. Defendants were entitled to rely upon the "state of the art" at the time the Prolift device was made. In determining whether Defendants used state-of-the-art techniques when the Prolift was made, you should consider the following:

(1) Scientific and technical knowledge available;

(2) Industry methods of design, including techniques of manufacturing, labeling, and warning;

(3) Industry safety standards; and

(4) Inspecting and testing by other manufacturers of similar products.

If you find that the Prolift device conformed to the state of the art as of April 17, 2006, then you may find for Defendants on Plaintiff's negligence claim.[7]

[7] W.L. Prosser, *Handbook of the Law of Torts* § 96 at 641, 644-45 (4th ed. 1971); *see O'Connor, v. Davis, et al.*, 2000 WL 35516915 (Or. Cir. Mar. 19, 2000) (striking state of the art defense to strict liability failure to warn claim, but recognizing that "the parties agree that this defense is an appropriate response to that portion of plaintiff's product liability claims based on negligence").

DEFENDANTS' PROPOSED INSTRUCTION NO. 8

(Negligence: Availability of an Alternative, Feasible Design)

In deciding whether Defendants acted with "reasonable care" in designing the Prolift, you may also consider whether a reasonable alternative design to Prolift was feasible at the time of Plaintiff's surgery and would have reduced or avoided any foreseeable risks of harm posed by the Prolift device.[8]

[8] *Donaca v. Curry Cnty.*, 734 P.2d 1339, 1344 (Or. 1987); *see Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013) (contention that drug manufacturer "stop selling" drug is not compatible with federal preemption standards); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–18 (2011) (state failure-to-warn claim preempted by the FDCA because it was impossible for drug manufacturer to comply with both state-law duty to label their products in way that rendered them reasonably safe and the federal-law duty not to change their drugs' labels).

DEFENDANTS' PROPOSED INSTRUCTION NO. 9

(Negligence: Foreseeability)

Defendants can only be held liable for the reasonably foreseeable consequences of their actions. There are two things that must be foreseeable. Plaintiff must show (1) that she is within the general class of persons that one reasonably would anticipate might be threatened by Defendants' allegedly negligent conduct and (2) that the harms she allegedly suffered are within the general class of harms one reasonably would anticipate might result from that conduct.

If you find that some person or force other than Defendants produced Plaintiff's injuries after Defendants' allegedly negligent conduct, you must decide whether that person or force prevents them from being liable for Plaintiff's alleged injuries.[9]

[9] Oregon Uniform Civil Jury Instruction No. 20.03; *Leavitt v. Stamp*, 293 P. 414, 416 (Or. 1930); *Oregon Steel Mills, Inc. v. Coopers Lybrand, LLP*, 83 P.3d 322, 345 (Or. 2004).

DEFENDANTS' PROPOSED INSTRUCTION NO. 10

(Negligence: Causation)

You cannot find for Plaintiff on her negligence claim unless she proves that Defendants' alleged negligence proximately caused her alleged injuries. Defendants' alleged negligence proximately caused those injuries only if they would not have occurred without such negligence. Conversely, Defendants' alleged negligence is not a cause of Plaintiff's alleged injuries if those injuries would have occurred without that conduct. Proximate cause is also not established if some other unforeseeable person or force intervened to cause Plaintiff's alleged injuries and made Defendants' allegedly negligent conduct a remote cause.

Thus, if Dr. Wheat would have prescribed the Prolift even if Defendants had not negligently warned of its risks, as Plaintiff alleges, then Defendants' warning did not proximately cause Plaintiff's injuries. Likewise, if Plaintiff would have experienced the same injuries had Defendants not designed the Prolift in the manner Plaintiff alleges was negligent, then that design did not proximately cause Plaintiff's injuries.

If you cannot conclude that Defendants' alleged negligence proximately caused Plaintiff's injuries without speculating, you must find for Defendants. The causal connection between Defendants' alleged negligence and Plaintiff's alleged injuries must be reasonably probable, not merely possible.[10]

[10] Oregon Uniform Civil Jury Instruction Nos. 23.01, 23.02; *Parkinson v. Novartis Pharmaceuticals, Corp.*, 5 F. Supp. 3d 1265, 1273 (D. Or. 2014); *Sims v. Dixon*, 355 P.2d 478, 480 (Or. 1960); *Trees v. Ordonez*, 311 P.3d 848, 861 (Or. 2013); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 526, 529 (Or. 1974) (in "negligence action" against drug manufacturer, "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient").

DEFENDANTS' PROPOSED INSTRUCTION NO. 11

(Strict Liability for a Defective Product)

I will now instruct you on the law of strict liability for a defective product, which forms the basis for two of Plaintiff's claims: strict liability—design defect, and strict liability—failure to warn.

The law assumes that products manufactured and sold are not unreasonably dangerous for their intended use. However, Defendants may be held liable for physical harm to Plaintiff caused by the Prolift's alleged defects if Plaintiff proves that the Prolift was in a "defective condition."[11]

[11] Oregon Uniform Civil Jury Instruction Nos. 48.01; O.R.S. § 30.920(1); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1099 (D. Or. 2013); *see Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 127-136 (2017) (reversing and remanding because jury's verdicts that defendant was liable for negligent failure to warn but not strictly liable for failure to warn were "fatally inconsistent"); Restatement (Third) of Torts: Prod. Liab. § 2 (1998) (discussing the "mischief caused" in design defect cases by allowing negligence to proceed to the jury where the strict liability design defect claim has failed).

DEFENDANTS' PROPOSED INSTRUCTION NO. 12

(Strict Liability for a Defective Product: "Defective Condition" Defined)

"Defective condition" means that when the product left Defendants' hands, it was in a condition that was "unreasonably dangerous" to Plaintiff. A product is "unreasonably dangerous" when it is more dangerous than contemplated by the ordinary consumer who purchases the product with the ordinary knowledge common to those purchasers. In this case, the ordinary consumers are pelvic floor surgeons.

A product may be in a "defective condition" because of (1) its design or (2) the absence of adequate warnings or instructions.[12]

Given: _____
Given as Modified: _____
Refused: _____
Withdrawn: _____

[12] Oregon Uniform Civil Jury Instruction Nos. 48.02 and 48.03; O.R.S. § 30.920(1); *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1099 (D. Or. 2013); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974); *Guevara v. Dorsey Labs., Div. of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1988) (citing Comment i to Restatement (Second) of Torts § 402A for the rule that, on the issue of duty to warn, the question is "whether the product as sold was 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it [again, in the case of prescription drugs, the general practitioner who prescribes it], with *the ordinary knowledge common to the community* as to its characteristics." (emphases and alterations in original; quotations omitted)).

DEFENDANTS' PROPOSED INSTRUCTION NO. 13

(Strict Liability: Inherent Risks)

Some useful products are inherently dangerous and cannot be made safe for their ordinary use. An example is a knife. A knife is not defective because it is sharp or can cut something because that is the very purpose of a knife. Products which are incapable of being made completely safe for their intended and ordinary use are especially common in the field of prescription drugs and medical devices, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of a physician.

Products that contain inherent dangers are not defective simply because they are dangerous so long as they are properly designed.

If you find the risk that injured Plaintiff was an inherent risk of the Prolift device, you may find that the device is not defective.[13]

Given: _____
Given as Modified: _____
Refused: _____
Withdrawn: _____

[13] O.R.S. § 30.920(3); Restatement (Second) of Torts § 402A, cmt. *k* (1965); *Senn v. Merrell-Dow Pharms., Inc.*, 751 P.2d 215 (Or. 1988); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1338 (9th Cir. 1985).

DEFENDANTS' PROPOSED INSTRUCTION NO. 14

(Strict Liability for a Defective Product: Design of the Product)

Because Prolift is not a common product, you can only find that the Prolift is "unreasonably dangerous" if Plaintiff proves the "ordinary" consumer's expectations about the Prolift's performance and safety. In this case, the "ordinary" consumers are pelvic floor surgeons. To do so, Plaintiff should submit evidence proving that the foreseeable risks of harm posed by the Prolift outweighed its utility.[14]

Given: _____
Given as Modified: _____
Refused: _____
Withdrawn: _____

[14] Oregon Uniform Civil Jury Instruction Nos. 48.02; *McCathern v. Toyota Motor Corp.*, 23 P.3d 320, 331 (Or. 2001) ("When a jury is 'unequipped either by general background or by facts supplied in the record, to decide whether [a product] failed to perform as safely as an ordinary consumer would have expected,' this court has recognized that additional evidence about the ordinary consumer's expectations is necessary. That additional evidence may consist of evidence that the magnitude of the product's risk outweighs its utility, which is often demonstrated by proving that a safer design alternative was both practicable and feasible.") (citations omitted); Restatement (Third) of Torts: Prods. Liab. § 2(b) & cmt. *f* (1998); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974); *Guevara v. Dorsey Labs., Div. of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1988) (citing Comment i to Restatement (Second) of Torts § 402A for the rule that, on the issue of duty to warn, the question is "whether the product as sold was 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it [again, in the case of prescription drugs, the general practitioner who prescribes it], with *the ordinary knowledge common to the community* as to its characteristics." (emphases and alterations in original; quotations omitted)).

DEFENDANTS' PROPOSED INSTRUCTION NO. 15

(Strict Liability: Necessity of an Alternative, Feasible Design)

In deciding whether the foreseeable risks of harm posed by the Prolift device outweighed its utility, you should consider whether those harms could have been reduced or avoided if Defendants had adopted a reasonable alternative design. There are many designs which, although they may eliminate a particular risk, are not practicable to produce. To prove that a design is defective, Plaintiff must prove that there was an alternative, feasible design that would have eliminated the risk that injured her.

To make this showing, Plaintiff must present expert testimony, grounded in reasonable medical or scientific certainty, establishing:

(a) The alternative design would be effective and suitable for Plaintiff.

(b) The alternative design would not be less safe than the Prolift device overall. In other words, it must not pose new risks that are more serious than those posed by the Prolift device.

(c) The alternative design was technologically and economically feasible at the time the Prolift device was manufactured.

(d) The alternative design would have eliminated the risk of Plaintiff's specific injuries.

(e) The alternative design was legally available for sale in the United States when the Plaintiff received her implant.

The alternative design must be an alternative, commercially available way to design the Prolift device. In other words, procedures that do not involve a mesh implant, such as alternative surgeries or non-mesh products, cannot be used to establish a safer alternative design.[15]

[15] *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1326 (Or. 1978); *McCathern v. Toyota Motor Corp.*, 23 P.3d 320, 331 (Or. 2001) ("When a jury is 'unequipped either by general background or by facts supplied in the record, to decide whether [a product] failed to perform as safely as an ordinary consumer would have expected,' this court has recognized that additional evidence about the ordinary consumer's expectations is necessary. That additional evidence may consist of evidence that the magnitude of the product's risk outweighs its utility, which is often demonstrated by proving that a safer design alternative was both practicable and feasible.") (citations omitted); *Purdy v. Deere & Co*., 386 P.3d 2, 7 (Or. Ct. App. 2016); Restatement (Third) of Torts: Prods. Liab. § 2(b) & cmt. *f* (1998); *Hornbeck v. Danek Medical, Inc.*, 2000 WL 1028981, at *1 (5th Cir. Jul. 5, 2000) (in table at 226 F.3d 641); *Hurley v. Motor Coach Indus., Inc.*, 222 F.3d 377, 380 (7th Cir. 2000); *Salvio v. Amgen Inc.,* 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012); *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. 2013); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 852 (N.Y. 2003); *Conklin v. Novartis Pharmas., Corp.*, 2012 WL 4127295, *8 (E.D. Tex. Sept. 18, 2012); Restatement (Third) of Torts: Prod. Liab. § 2 & cmt. *f*; *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1056–57 (11th Cir. 1994); *Malen v. MTD Prod., Inc*., 628 F.3d 296, 308 (7th Cir. 2010); *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 339 (Tex. 1998); *see Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013) (contention that drug manufacturer "stop selling" drug is not compatible with federal preemption standards); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617–18 (2011) (state failure-to-warn claim preempted by the FDCA because it was impossible for drug manufacturer to comply with both state-law duty to label their products in way that rendered them reasonably safe and the federal-law duty not to change their drugs' labels).

DEFENDANTS' PROPOSED INSTRUCTION NO. 16

(Strict Liability for a Defective Product: Failure to Warn or Instruct)

To prevent a product like Prolift from being "unreasonably dangerous," a manufacturer may be required to warn or instruct pelvic floor surgeons regarding the use of the product. Manufacturers are not, however, required to warn or instruct pelvic floor surgeons with regard to a danger that is generally known and recognized. If you determine that the product would be unreasonably dangerous in the absence of an adequate warning or instruction, and if you determine that an adequate warning or instruction did not accompany the product, then the product was unreasonably dangerous.

If, however, you find that Defendants provided adequate warnings and instructions to pelvic floor surgeons regarding the Prolift device, such that it is safe for use if the warnings and/or instructions are followed, the device was neither in a defective condition nor unreasonably dangerous.[16]

[16] Oregon Uniform Civil Jury Instruction No. 48.07; *Parkinson v. Novartis Pharms., Corp.*, 5 F. Supp. 3d 1265, 1267, 1273–74 (D. Or. 2014); *Terhune v. A. H. Robins Co*., 577 P.2d 975, 978 (Wash. 1978); *Luttrell v. Novartis Pharms.*, Corp. 555 F. App'x 710, 710–11 (9th Cir. 2014).

DEFENDANTS' PROPOSED INSTRUCTION NO. 17

(Strict Liability: Causation)

You cannot find for Plaintiff on either of her strict liability claims unless she proves that the specific "defective condition" created by Defendants' alleged design defect and/or inadequate warnings proximately caused her alleged injuries. Defendants' alleged design and/or warning defect caused those injuries only if they would not have occurred without the defect. Conversely, Defendants' alleged defect did not proximately cause Plaintiff's alleged injuries if those injuries would have occurred without the alleged defect, or if the defect was not a substantial cause of those injuries. Nor would the defect proximately cause Plaintiff's alleged injuries if some other unforeseeable person or force intervened to cause those injuries and made the defect a remote cause.

Thus, if Dr. Wheat would have prescribed the Prolift even if Defendants had adequately warned of its risks then Defendants' allegedly inadequate warning did not proximately cause Plaintiff's injuries. Likewise, if Plaintiff would have experienced the same injuries had Defendants not designed the Prolift in the manner Plaintiff alleges was defective, then that allegedly defective design did not proximately cause Plaintiff's injuries.

If you cannot conclude that Defendants' alleged design defect and/or inadequate warnings proximately caused Plaintiff's injuries without speculating, you must find for Defendants. In other words, the causal connection between the alleged defect and Plaintiff's injuries must be reasonably probable, not merely possible.[17]

[17] O.R.S. § 30.920; *Parkinson v. Novartis Pharms., Corp.*, 5 F. Supp. 3d 1265, 1267, 1273–74 (D. Or. 2014); *Crosswhite v. JumpKing, Inc.*, 411 F. Supp. 2d 1228, 1235 (D. Or. 2006); *Gilmour v Norris Paint & Varnish, Co.*, 627 P.2d 1288, 1291 (Or. 1981); *Findlay v. Copeland*

DEFENDANTS' PROPOSED INSTRUCTION NO. 18

(Comparative Fault)

1. "Comparative fault" is a defense to all of Plaintiff's claims other than fraud. If you find that Plaintiff's claimed injuries were the result of fault by both Defendants and Plaintiff, then you must compare the fault of Plaintiff to the fault of Defendants.

2. In making that comparison, you must assign percentages of fault to each party, and the total percentages should equal 100 percent. If Plaintiff's fault is more than 50 percent, then you must return a verdict for Defendants. On the other hand, if Plaintiff's fault is 50 percent or less, then your verdict is for Plaintiff.

Do not reduce the amount of Plaintiff's damages, if any, as a result of your comparison of fault. I will reduce the amount of your verdict by the percentage of Plaintiff's fault, if any.[18]

Lumber Co., 509 P.2d 28, 30 (Or. 1973); *Phelps v. Wyeth, Inc*., 938 F. Supp. 2d 1055, 1068 (D. Or. 2013); *Vandermay v. Clayton*, 984 P.2d 272, 277 (Or. 1999).

[18] Oregon Uniform Civil Jury Instruction Nos. 21.01, 21.02; *Sandford v. Chevrolet Div. of Gen. Motors*, 642 P.2d 624, 626 (Or. 1982).

DEFENDANTS' PROPOSED INSTRUCTION NO. 19

(Fraud)

You cannot find for Plaintiff on her claim of fraud unless she proves all of the following by "clear and convincing" evidence:

(1) Defendants made a false representation on a "material matter";

(2) Defendants knew the representation was false or recklessly made the representation without knowing if it was true or false;

(3) Defendants intended to mislead Plaintiff, knew they were misleading Plaintiff, or recklessly disregarded whether they were misleading Plaintiff;

(4) Plaintiff reasonably relied on the false representation; and

(5) Plaintiff was damaged as a direct result of her reliance on the false representation.

Evidence is "clear and convincing" where the truth of the facts asserted are highly probable.

A false representation on a "material matter" is one that would be likely to affect the conduct of a reasonable person with regard to a transaction.[19]

[19] Oregon Uniform Civil Jury Instruction Nos. 42.01, 42.02, 42:10; *Riley Hill Gen. Contractor, Inc. v. Tandy Corp.*, 737 P.2d 595, 605 (Or. 1987).

DEFENDANTS' PROPOSED INSTRUCTION NO. 20

(Fraud: Reasonable Reliance)

In determining whether Plaintiff's reliance on the statements of Defendants was reasonable, you must consider the totality of the parties' circumstances and conduct. In doing so, you may consider factors such as:

(1) Any information known or obvious to Plaintiff or Dr. Wheat to confirm or refute Defendants' allegedly false statement(s), as well as any diligence on those persons' part to do so;

(2) The relative status, knowledge, and experience of Plaintiff, Dr. Wheat, and Defendants;

(3) The previous experience of Plaintiff, Dr. Wheat, and Defendants in similar transactions;

(4) Whether the statement was specific or general; and

(5) Whether the statement was a statement of fact or the expression of an opinion.

In deciding whether a statement is a statement of an opinion or a representation of fact, you should consider the circumstances under which the statement was made.[20]

[20] Oregon Uniform Civil Jury Instruction Nos. 42.06, 42.07; *Oregon Pub. Employees' Ret. Bd. ex rel. Oregon Pub. Employees' Ret. Fund v. Simat, Helliesen & Eichner*, 83 P.3d 350, 361 (Or. Ct. App. 2004).

DEFENDANTS' PROPOSED INSTRUCTION NO. 21

(Fraud: Representation Made to Third Party)

A false representation does not have to be made directly to the plaintiff. But in order for Plaintiff to show that Defendants defrauded her by making a false representation to another person, Plaintiff must prove that Defendants intended for the other person to communicate the false representation to Plaintiff or a person like her.[21]

[21] Oregon Uniform Civil Jury Instruction No. 42.08; *Carpenter v. Egli*, 536 P.2d 1236, 1237 (Or. 1975); *Est. of Schwarz v. Philip Morris Inc.*, 135 P.3d 409, 424 (Or. Ct. App. 2006).

DEFENDANTS' PROPOSED INSTRUCTION NO. 22

(Fraud: Concealment)

A person may make a false representation on a material matter by concealing the truth. To prove a false representation by concealment, Plaintiff must show that Defendants made some representation, or took some action, to intentionally prevent Plaintiff from acquiring information on a material matter, thereby creating a false impression or covering up the truth.[22]

[22] Oregon Uniform Civil Jury Instruction Nos. 42.05; Restatement (Second) of Torts § 550 (1977).

DEFENDANTS' PROPOSED INSTRUCTION NO. 23

(Warranties)

Contracts for the sale of goods may contain "warranties." A warranty can be made expressly or impliedly. Plaintiff alleges that Defendants made certain express and implied warranties regarding the Prolift device that Defendants later breached. You must determine whether any such warranties existed and, if so, whether Defendants breached any of them.[23]

[23] Oregon Uniform Civil Jury Instruction Nos. 67.01; O.R.S. § 72.3130.

DEFENDANTS' PROPOSED INSTRUCTION NO. 24

(Warranties: Existence of Express Warranties)

If Defendants made an affirmation of fact or promise to the buyer regarding the Prolift device, and such affirmation or promise was a basis for the parties' bargain, then Defendants created an express warranty that the Prolift device would conform to that affirmation or promise. Additionally, if Defendants provided a description of the Prolift device that was a basis for the parties' bargain, then Defendants created an express warranty that the goods would conform to that description.

An express warranty may be created without using formal words such as "warrant" or "guarantee" or any specific intention to create an express warranty. However, an affirmation merely of the value of the goods or a statement presented as merely the seller's opinion or commendation of the goods does not create an express warranty.[24]

[24] Oregon Uniform Civil Jury Instruction No. 67.02; O.R.S. § 72.3130.

DEFENDANTS' PROPOSED INSTRUCTION NO. 25

(Warranties: Breach of Express Warranties)

To recover damages for breach of an express warranty, Plaintiff must prove all of the following elements:

(1) Defendants made one or more express warranties relating to the Prolift device;

(2) Defendants breached one or more of the express warranties because the Prolift device did not conform to one or more of the express warranties;

(3) Plaintiff notified Defendants of the breach within a reasonable time after she discovered or should have discovered the breach; and

(4) Plaintiff sustained damages as a result of Defendants' breach.[25]

[25] Oregon Uniform Civil Jury Instruction No. 67.03.

DEFENDANTS' PROPOSED INSTRUCTION NO. 26

(Warranties: Implied Warranty of Fitness)

An implied warranty of fitness for a particular purpose arises where the seller at the time of contracting has reason to know that:

(1) The goods are required for a particular purpose; and

(2) The buyer is relying on the seller's skill or judgment to select or furnish suitable goods.

In deciding whether an implied warranty of fitness exists, you may consider the knowledge and skill of Plaintiff, implanting physicians, and Defendants.[26]

[26] Oregon Uniform Civil Jury Instruction No. 67.04; O.R.S. § 72.3150; *Valley Iron & Steel Co. v. Thorin*, 562 P.2d 1212, 1217 (Or. 1977).

DEFENDANTS' PROPOSED INSTRUCTION NO. 27

(Warranties: Breach of Implied Warranty of Fitness)

To recover damages for breach of an implied warranty of fitness for a particular purpose, Plaintiff must prove the following elements:

(1) Defendants sold the Prolift device to the buyer;

(2) Defendants impliedly warranted that the Prolift device would be suitable for treating pelvic organ prolapse;

(3) The Prolift device was not suitable for the particular purpose warranted;

(4) Plaintiff notified Defendants of the breach within a reasonable time after she discovered or should have discovered the breach; and

(5) Plaintiff sustained damages resulting from Defendants' breach.[27]

[27] Oregon Uniform Civil Jury Instruction No. 67.05.

DEFENDANTS' PROPOSED INSTRUCTION NO. 28

(Warranties: Causation)

You cannot find for Plaintiff on any of her warranty claims unless she proves that Defendants' alleged breach of warranties proximately caused her alleged injuries. Defendants' alleged breach proximately caused those injuries only if they would not have occurred without the alleged breach of warranty. Conversely, Ethicon's alleged breach is not a cause of Plaintiff's alleged injuries if those injuries would have occurred without the alleged breach of warranty. Nor would the alleged breach of warranty be the proximate cause of Plaintiff's alleged injuries if some other unforeseeable person or force intervened to cause those injuries and made the alleged breach of warranty a remote cause.

If you cannot conclude that Defendants' alleged breach caused Plaintiff's injuries without speculating, you must find for Defendants. In other words, the causal connection between the alleged breach of warranty and Plaintiff's injuries must be reasonably probable, not merely possible.[28]

[28] O.R.S. § 30.920; *Taylor v. Ramsay-Gerding Const. Co.*, 226 P.3d 45, 55 (Or. Ct. App. 2010) (to prove warranty claim, "buyer must demonstrate the existence of proximate cause between the seller's breach and the buyer's loss") (citing Larry Lawrence, *Anderson on the Uniform Commercial Code* § 2-314:612 (3d ed. 1996-2002) ("the conduct of the plaintiff is a defense to warranty liability to the extent that it shows that the proximate cause of the plaintiff's harm was not the breach of warranty")); *Chong v. STL Int'l, Inc.*, 152 F. Supp. 3d 1305, 1318 (D. Or. 2016); *Joshi v. Providence Health Sys. of Oregon Corp.*, 149 P.3d 1164, 1167 (Or. 2006); *Trees v. Ordonez*, 311 P.3d 848, 861 (Or. 2013); *Hills v. McGillvrey*, 240 Or. 476, 481, 402 P.2d 722, 724 (Or. 1965); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1068 (D. Or. 2013); *Vandermay v. Clayton*, 984 P.2d 272, 277 (Or. 1999).

DEFENDANTS' PROPOSED INSTRUCTION NO. 29

(Causation: Necessity of Proof By Expert Testimony)

As I have explained, each of Plaintiff's claims require her to show that her injuries were proximately caused by Defendants. Because of the complex nature of her claims, Plaintiff can only prove Defendants proximately caused her alleged injuries through expert testimony. This means that if you do not accept the testimony of Plaintiff's medical experts regarding the cause(s) of Plaintiff's alleged injuries, then you must find for Defendants on all of Plaintiff's claims.[29]

[29] *Vandermay v. Clayton*, 984 P.2d 272, 277 (Or. 1999); *Phelps v. Wyeth, Inc*., 938 F. Supp. 2d 1055, 1068 (D. Or. 2013); *Chouinard v. Health Ventures*, 39 P.3d 951, 954 (Or. Ct. App. 2002).

DEFENDANTS' PROPOSED INSTRUCTION NO. 30

(Statute of Limitations & Discovery Rule—Personal Injury)

Defendants allege that Plaintiff filed her personal injury claim after the time limit set by the "statute of limitations." The statute of limitations sets a time limit within which a plaintiff must file her lawsuit.

Plaintiff filed her lawsuit on August 28, 2012. This means that you must find for Defendants on Plaintiff's negligence, strict liability, and fraud claims if Defendants prove that, by August 28, 2010, Plaintiff knew or should have known of a substantial possibility that problems with the Prolift's design or warnings caused harm to Plaintiff.[30]

[30] Oregon Uniform Civil Jury Instruction No. 17.03; O.R.S. § 12.110 (two-year limitations period for personal injury claims), O.R.S. § 30.905 (actions may not be commenced outside applicable limitations period); *Kambury v. DaimlerChrysler Corp*., 60 P.3d 1103, 1105 (Or. Ct App. 2003) (applying two-year statute of limitations under ORS § 30.905 to claims for strict products liability, negligence, breach of warranty, and misrepresentation).

DEFENDANTS' PROPOSED INSTRUCTION NO. 31

(Statute of Limitations—Breach of Warranty)

Defendants also allege that Plaintiff filed her breach of warranty claim after the time limit set by the "statute of limitations" that applies to that claim. Again, the statute of limitations sets a time limit within which a plaintiff must file her claim.

Plaintiff filed her lawsuit on August 28, 2012. This means that you must find for Defendants on Plaintiff's breach of warranty claims if Defendants prove that Defendants' alleged breach of warranty occurred before August 28, 2008. Generally speaking, a breach of warranty occurs when a product is delivered to the consumer. In this case, the Prolift device was delivered to Plaintiff on April 17, 2006, the date of her implantation surgery. There is, however, an exception for warranties about how the product will perform in the future; under such circumstances, the breach of warranty does not occur until the Plaintiff discovers, or reasonably should have discovered, the breach.[31]

[31] O.R.S. § 72.7250(1)-(2) (accrual rule and four-year limitations period for UCC claims, including breach of warranty); O.R.S. § 30.905 (actions may not be commenced outside applicable limitations period); *Redfield v. Mead*, *Johnson & Co.*, 512 P.2d 776, 777 (Or. 1973) (holding that four-year UCC limitations period, rather than two-year personal injury limitations period, applies to claim against drug manufacturer "to recover damages for personal injuries resulting from the alleged breach of an implied warranty that the drug was fit for the purpose for which it was sold to [plaintiff]").

DEFENDANTS' PROPOSED INSTRUCTION NO. 32

(Damages)

If you find for Plaintiff on any of her claims, then you must decide whether Plaintiff has been damaged and, if so, the amount of her damages.

The fact that I am instructing you with respect to damages is not to be considered by you as an attempt by this Court to suggest that you should or should not award damages.

There are two types of compensatory damages alleged in this case: economic damages and noneconomic damages. Plaintiff must prove economic and noneconomic damages by a preponderance of the evidence. I will now explain each of these two types of damages.[32]

[32] Oregon Uniform Civil Jury Instruction No. 70.01.

DEFENDANTS' PROPOSED INSTRUCTION NO. 33

(Noneconomic Damages)

Noneconomic damages are the subjective, nonmonetary losses that the Plaintiff has sustained or probably will sustain in the future.

The law does not provide you with any fixed standard by which to measure the exact amount of noneconomic damages. However, the law requires that all damages awarded be reasonable. You must apply your own considered judgment, therefore, to determine the amount of noneconomic damages.

In determining the amount of noneconomic damages, if any, consider any pain, mental suffering, or emotion distress that Plaintiff has sustained, and probably will sustain in the future, as a result of the injuries she alleges Defendants proximately caused.[33]

[33] Oregon Uniform Civil Jury Instruction No. 70.02.

DEFENDANTS' PROPOSED INSTRUCTION NO. 34

(Economic Damages)

Economic damages are the objectively verifiable monetary losses that the plaintiff has incurred or will probably incur. In determining the amount of economic damages, if any, consider:

(1) The reasonable value of necessary medical services for treatment of the Plaintiff.

(2) The amount of lost income incurred by the Plaintiff since the injury to date.[34]

[34] Oregon Uniform Civil Jury Instruction No. 70.03.

DEFENDANTS' PROPOSED INSTRUCTION NO. 35

(Damages: Aggravation of Existing Injury)

In the present case, Plaintiff has alleged that Defendants' conduct caused her injuries, some of which may or may not have been an aggravation of Plaintiff's preexisting injuries. In determining the amount of damages, if any, to be awarded the Plaintiff, you may allow her reasonable compensation for the consequences of any such aggravation that you find resulted from Defendants' alleged misconduct. However, you should not award her any damages for any earlier condition or injury, but only those injuries that are due to its enhancement or aggravation.[35]

[35] Oregon Uniform Civil Jury Instruction No. 70.07.

DEFENDANTS' PROPOSED INSTRUCTION NO. 36

(Damages: Mitigation)

A person who suffers damage has a duty to exercise reasonable care to avoid increasing that damage. There can be no recovery for increased damage caused by the failure to exercise such care.[36]

[36] Oregon Uniform Civil Jury Instruction No. 73.01.

DATED: June 13, 2022

BULLIVANT HOUSER BAILEY PC

By */s/ Jeanne F. Loftis*
Jeanne F. Loftis, OSB #913612
Nelly F. Greenberg, OSB #201968
Telephone: 503.228.6351

BUTLER SNOW LLP

By */s/ Kenneth Conour*
Kenneth Conour, admitted *pro hac vice*
Telephone: 615.651.6715
Anita Modak-Truran, admitted *pro hac vice*
Telephone: 615.651.6751
Jin Yoshikawa, admitted *pro hac vice*
Telephone: 615.651.6622

Attorneys for Defendants

4871-5892-0485.1 37519/00008